

REMARKS

This Amendment is respectfully submitted in response to the Office Action rendered June 28, 2001. It is timely submitted in view of the Petition for Extension of Time submitted concurrently herewith.

Claims 26-28 have been added in order to describe certain embodiments of the compositions of applicants' invention. They find basis in the Specification at page 10, lines 6-8, page 10, lines 14-16, page 10, lines 18-28, page 11, lines 1-2 and page 11, line 16. A marked-up copy of the claims is submitted concurrently herewith as an Appendix to this Amendment.

Reference to the provisional patent applications from which the above-captioned patent application claims the benefit of priority under 35 U.S.C. 119(e) has been added to the Specification. No new matter has been added as these applications are referred to in the cover letter for the non-provisional application.

The Office Action of June 28, 2001 rejected claims 1-12 and 15-25 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action noted that the Markush group set forth in claims 1 and 25 had the term "or" rather than the term --and-- . In order to correct this inadvertent error and restore proper Markush terminology to the claims, applicants have amended claims 1 and 25 to include the term --and-- . Applicants respectfully request reconsideration of this rejection in view of this correction.

The Office Action of June 28, 2001 rejected claims 1-10 and 12-25 under 35 U.S.C. 103(a) as being unpatentable over either De Stoutz (U.S. 5,503,832) or JP 62036394 (Abstract) in view of Bissett et al. (U.S. 6,183,761) and Knight et al. (U.S. 6,017,549). Applicants respectfully request reconsideration of this rejection in light of the ensuing discussion, the publications submitted herewith and the Declaration of Jonathan Miller submitted herewith.

The basis for the rejection was as follows:

De Stoutz teaches using soymilk in skin care products and other cosmetic products...JP 62036304 ...teaches using soybean milk in cosmetic compositions for skin and hair. Neither reference explicitly teaches a stabilizing system of the instant invention. However, the claimed stabilizing system comprising an antioxidant...a chelating agent...and/or a preservative...is known and widely used in the art of

cosmetic compositions for the purpose of stabilizing active ingredients...[Office Action, 6/27/01, p. 3]

Applicants respectfully submit that neither De Stoutz nor JP 62036394 suggests or describes the compositions or methods of applicants' invention, as pointed out in the Office Action. De Stoutz relates to "a method for extracting the soluble material from oil-bearing beans or seeds and, more particularly with a method for manufacturing a 'milk' or creams based on such oil-bearing seeds." [De Stoutz, Col. 1, l. 6-10]. However, De Stoutz actually teaches away from the compositions of applicants' invention, as it suggests that "nutritionally undesirable" factors should be reduced, i.e., denatured, during:

Also, because of the very short contact time of the seeds with water which is preferably at 80° C., a considerable decrease in the bacterial load is achieved, as well as in the amount of factors which, in the case of food products, are nutritionally undesirable (antitrypsin factors). [Col. 2, l. 59-63] (emphasis added)

These "nutritionally undesirable" factors, antitrypsin factors (also known as trypsin inhibitory factors), are the very measure of biological activity which applicants' state as marking a "nondenatured" composition according to their invention [See Specification, page 7, lines 12-14]. In contrast, De Stoutz thus suggests that pre-soaking tends to increase the amount of enzymes in the final product. In fact, Fig. 3 of De Stoutz demonstrates the reduction of antitrypsin content without pre-soaking, indicating that including such compounds in the final product is undesirable. Even in cosmetic products, De Stoutz suggests that the compositions be subjected to a heat treatment, which tends to denature proteins such as trypsin inhibitors:

Clearly, for a proper conservation of the products obtained, when the soy milks and creams are designed for use in skin care, it may be necessary to subject these products to a thermal treatment. This thermal treatment can advantageously be carried out using the Joule effect according to the method described in EP 0.476.311. [Col. 4, l. 12-17]

Thus, De Stoutz neither suggests nor describes the compositions or methods of applicants' invention.

Nor does the JP 62036304 publication suggest or describe the compositions of applicants' invention. The JP 62036304 publication merely indicates that cosmetics containing soya milk may be used for cleaning and moisturizing the skin and hair. Nowhere does it suggest or describe the stable compositions or novel methods of applicants' invention. At the time of the JP 62036304 publication, soy products containing was known to cause pancreatic

enlargement and intestinal discomfort. As set forth in the articles appended hereto, at the time of the JP 62036304 publication, it was desirable to treat soy products so as to denature the proteins contained therein [See "Inhibition of Human and Rat Pancreatic Proteinase by Crude and Purified Soybean Proteinase Inhibitors, Krogdahl et al., *J. Nutr.* 109: 551-558, 1979; "Structure-Function Relationships of proteinase Inhibitors from Soybean (Bowman-Birk) and Lima Bean", E. Kay, *The Journal of Biological Chemistry*, Vol 254, No. 16, Issue of August 25, pp. 7648-7650, 1979; and "The Effects of Soybean Trypsin Inhibitors on the Pancreas of Animals and Man: A Review", D. F. Flavin, *Vet Hum Toxicol*, 24, pp. 25-28, 1982]. Nowhere does JP 62036304 suggest or describe a different treatment for the soy-containing products it mentions in order to retain the presence of soy trypsin inhibitor or other proteins that were known to be dangerous when ingested.

In contrast, the methods and compositions of applicants' invention contain non-denatured soy products. As set forth in the Specification at page 12, line 15 through page 14, line 27, the applicants' have found that soy proteins such as Soy Trypsin Inhibitor act, for example, to depigment skin, reduce skin oiliness and shine, treat or prevent the condition of acne, relieve pain and burning after sun exposure even the tone and texture of skin, and increase elastic properties of skin. Neither De Stoutz patent nor the JP 620363304 abstract describes or suggests either non-denatured soy- or legume-containing compositions nor these methods of using such compositions to treat or prevent the aforementioned skin conditions.

Nor do the Bissett et al. or Knight et al. patents remedy the deficiencies of De Stoutz and/or JP 62036304 in rendering the compositions of applicants' invention obvious. Bissett et al., for examples, relates to compositions containing a vitamin B3 compound and certain specific compounds such as flavanones. It lists at least two dozen "optional components" that may be included in these compositions, but nowhere suggests or describes the soy product-containing compounds of applicants' invention. Bissett et al. neither recognizes nor solves the problem of formulating soy- or legume-containing compositions as to maintaining non-denatured products in a physically or chemically stable formulation. Rather, Bissett et al. focuses on vitamin B3 compounds and compounds that may be extracted from soy products, but may also be synthesized [Col. 9, l. 13-17]. Furthermore, the "optional components" set forth at col. 10, l. 47-50 of Bissett et al. are described as optional, i.e. they need not be present in the composition. Thus, one of ordinary skill in the art would not

have looked to Bissett et al. to solve the stability problems of formulating with non-denatured soy protein products, particularly of soy milk.

Knight et al. was cited as containing caffeine powder. However, while the compositions of applicants' invention may contain caffeine as an anti-cellulite active ingredient, nothing in Knight et al. would have directed one of ordinary skill in the art toward formulating caffeine compositions with non-denatured soy protein products in a manner similar to the compositions of applicants' invention. Knight et al. neither recognizes such a possibility nor suggests a means for solving problems ensuing therefrom.

That it was not clear to one of ordinary skill in the art how to solve the physical and chemical stability problems of formulating with non-denatured soy protein products is set forth in the accompanying Declaration of Jonathan D. Miller. As demonstrated therein, during the course of developing compositions containing non-denatured soy products that retained their biological activity and were physically and chemically stable, Compositions A and B were formulated [Declaration of Jonathan D. Miller, ¶¶2, 3]. These compositions both failed to meet physical and chemical stability requirements for cosmetic compositions.

Composition A, for example, contained certain of the "optional components" set forth in Bissett et al., such as ascorbyl glucoside, an ascorbic acid derivatives, octyl methoxycinnamate, a sunscreen, retinol, and vitamin E (tocopherol). Yet, is resulted in a "chunky, lumpy, physically unstable product" (Declaration of Jonathan D. Miller, ¶5). Composition B also contained certain compounds set forth in Bissett et al. at col. 10, 119-36 and L. 40-57, such as salicylic acid, and ethanol. Composition B, too, was physically unstable as it "resulted in a sticky, clumpy product indicating that the product would not be usable as a topical cosmetic product" (Declaration of Jonathan D. Miller, ¶5). Rather, formulating the compositions of applicants' invention presented challenges due to the fact that not all thickeners and emulsifiers are compatible with non-denatured soy products (Declaration of Jonathan D. Miller, ¶6).

Neither Bissett et al. nor Knight et al. recognized these problems encountered in formulating non-denatured soy products, nor did either suggest or describe solutions for such problems. Indeed, when attempting to formulate such products utilizing some of the described elements of cosmetic compositions, the resulting compositions could not even be measured for chemical stability, due to their complete lack of physical stability.

Furthermore, none of the cited references suggests or describes compositions containing no more than 0.1% of a surfactant, as set forth in the embodiment of applicants' invention described in claim 2. In fact, JP 62036304 specifically suggests the use of more than 2% of a surfactant in soy milk compositions [See JP 62036304, Abstract]. Thus, the composition of claim 2 would not have been obvious in view of JP 62036304. As set forth in the Declaration of Jonathan D. Miller, formulating compositions containing non-denatured soy products was extremely difficult and even compositions containing conventional ingredients in conventional ranges were not successful.

Applicants therefore request reconsideration of the rejection under 35 U.S. 103(a) in view of De Stoutz or JP 62036304 in light of Bissett et al. and Knight et al. Not only does De Stoutz and JP 62036304 teach away from the compositions and methods of applicants' invention, the combination of these references with Bissett et al. and Knight et al. do not lead one of ordinary skill in the art toward the compositions and methods of applicants' invention. Not only would one of ordinary skill in the art not utilize non-denatured soy products in skin care products, based upon De Stoutz and JP 62036304, but they would not be able to formulate them into chemically or physically stable compositions using the descriptions set forth in Bissett et al. and Knight et al.

Claims 1-9, 11 and 13-25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (KR 9208853) in view of Bissett et al. and Knight et al. The basis for this rejection was that Lee et al. "teach[es] using soybean powder in cosmetics" [Office Action of 6/28/01, p. 4]. Applicants respectfully request reconsideration of this rejection in light of the discussion herein.

Lee et al. relates to a method of preparing soybean powder that includes selecting the soybeans, heating the soybeans, cutting the soybean grain, peeling the grain, steaming the peeled grain, drying and pulverizing the grain [Lee et al., Abstract]. While Lee et al. mentions that "the obtd. soybean powder is useful for the prodn. of food, cosmetic, etc." [Lee et al., Abstract], nowhere does Lee et al. suggest or describe the compositions or methods of applicants' invention.

Lee et al. actually suggests at least two steps in treating the soybeans that would denature the protein content of the beans: heating and steaming. Nowhere does Lee et al. suggest or describe steps that would preserve the trypsin inhibitory activity of the composition. In fact, in setting forth that the resulting powder would be useful in the

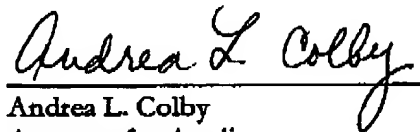
production of food and cosmetics, and in light of the contemporaneous knowledge that non-denatured soybean products were harmful, Lee et al.'s process would necessarily have included the denaturation of the enzymes in the soybean. Thus, Lee et al. teaches away from the compositions and methods of applicants' invention.

Nor do Bissett et al. or Knight et al. remedy the deficiencies of Lee et al. in leading one of ordinary skill in the art toward the compositions and methods of applicants' invention. As set forth above and in the accompanying Declaration of Jonathan D. Miller, following the descriptions set forth in Bissett et al. or Knight et al. would not result in physically or chemically stable compositions, even were they to suggest the possibility of formulating non-denatured soy powder or milk. Applicants therefore respectfully request reconsideration of the rejection of claims 1-9, 11 and 13-25 under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (KR 9208853) in view of Bissett et al. and Knight et al.

An Information Disclosure Statement and additional patents and publications are being submitted under separate cover for the consideration of the Patent and Trademark Office.

On the basis of the foregoing amendments to the claims and discussion, applicants respectfully request reconsideration of the rejections set forth in the Office Action of June 28, 2001 in light of the foregoing discussion, articles, and accompanying Declaration of Jonathan D. Miller. Consideration of new claims 26-29 is respectfully requested. An early allowance is earnestly solicited.

Respectfully submitted,



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APPENDIX

1. (Amended) A skin care composition for the topical delivery of a soy product comprising a non-denatured soy product and a stabilizing system, said stabilizing system comprising a member selected from the group consisting of an antioxidant, a chelating agent [or] and a preservative.

25. (Amended) A skin care composition for the topical delivery of a legume product comprising a non-denatured legume product and a stabilizing system, said stabilizing system comprising a member selected from the group consisting of an antioxidant, a chelating agent [or] and a preservative.